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TITLE: Continuous Pre-hospital Data as a Predictor of Outcome Following Major Trauma: A Study Using Improved and Expanded Data

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14. ABSTRACT This study is designed to acquire near continuous physiologic measurements, beginning at the earliest practical time after injury, on large numbers of injured patients with severe trauma. The study will utilize commercially available FDA-certified monitoring equipment, operating in a fleet of ground EMS ambulances currently serving a large metropolitan area with multiple trauma centers. First Responders may represent the earliest practical opportunity to acquire meaningful medical data in injury cases. This data will be correlated with significant clinical outcomes within the first 24 hours of admission and entered into a research database. This is the third annual report for the subject project. During the reporting period, the first of three planned Phase 2 data collection intervals using a new physiological monitor and expanded operations was conducted. Pre-hospital patient data was acquired and processed for 102 qualifying patient cases. Analysis further supports the hypothesis that ground EMS systems can provide an opportunity for earlier onset of pre-hospital patient data acquisition than helicopter services. Work continued to synchronize data collection methods with developing EMS electronic case data systems and to ensure retention of data needed for research in future EMS operations. Planning is underway to acquire and process additional pre-hospital patient data.

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Noninvasive, trauma, outcome, pre-hospital, EMS, predict, wireless, telemedicine

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Introduction

The reporting period for this report reflects work in Phase 2 of the project and is subject to previously approved and implemented modifications of the Phase 2 Statement of Work (SOW), dated December 15, 2006. The Phase 2 SOW was modified prior to the subject reporting period to reflect re-direction of some tasks pursuant to information that was gathered during preliminary research in Phase 1 and early Phase 2 operations. This report describes activities and accomplishments beginning after the modified SOW (dated December 15, 2006) for Phase 2 was approved, and prior to conduct of the first data collection interval using a different "new" physiological monitor and a significantly expanded scale of operations. The initial Phase 2 data collection interval resulted in acquisition of research patient data for 102 qualifying injury patients, including processing of the data for inclusion in a research database. Analysis of the 102 patient cases showed that the Mean Initial Data Delay (MIDD), which reflects the elapsed time between estimated time of injury and the start of pre-hospital data acquisition, continues to be significantly shorter for ground EMS (first responder) systems as compared to delays experienced within helicopter services. The MIDD findings are consistent with the hypothesis for the subject study, and reinforce the initial results found in limited Phase 1 data collection efforts. As reported herein, additional work on tasks within the approved SOW for Phase 2, including planning and preparations for conduct of the remaining data collection intervals, was continuing at the conclusion of the reporting period.

Ground Emergency Medical Services (EMS) may represent the earliest practical opportunity, for most civilian traumatic injury cases, to begin to acquire pre-hospital patient physiological data in support of the U.S. Army's "Combat Critical Care Engineering" (CCCE) research task area. This project represents one of the first attempts to accomplish large-scale operations within a large ground EMS system to collect the desired pre-hospital data for qualifying patients. The target patient population for this study includes adult trauma victims requiring code 3 (highest medical priority) field care and transport to participating Level 1 Trauma Centers. The data collected during the project work has been processed and provided for inclusion in the U.S. Army's Trauma Vitals database. The expanded scale of data collection operations was facilitated, in part, by the system-wide deployment of a new data-capable physiological monitor used during patient care and transport by the San Antonio Fire Department, Emergency Medical Services division (SA EMS).

The modified Phase 2 SOW added multiple data collection intervals of operations and included an accelerated initial data collection interval using the existing (but limited) new monitor configuration and SA EMS processes and procedures adapted to the features of the new monitor. Work was planned in the modified Phase 2 SOW to integrate further improvements in future project research data collection and processing operations with evolving upgrades in capabilities and procedures planned for both the new monitor and the SA EMS system. Additional data collection intervals planned for Phase 2 were to be coordinated with milestones in the evolving rollout of the monitor and SA EMS electronic case data system upgrades.

The activities and accomplishments reported in the Body section of this report reflect a relatively intense period of work early in the reporting period during conduct of the planned first (Phase 2) data collection interval. This included work with the new physiological monitor and resulting

new monitor data content and structure, and to address case organization and data processing improvements to meet the needs of the CCCE program. This work was followed by a period of relatively lower rates of activity during the reporting period focused on preparation for subsequent planned data collection intervals. During this time, Southwest Research Institute (SwRI®) continued work with SA EMS, the monitor manufacturer, U.S. Army Institute of Surgical Research (USAISR), and other relevant partners and vendors to try to facilitate the desired integration of planned future project data collection segments with evolving technical and procedural capabilities in routine SA EMS case data management operations. A no-cost time extension for Phase 2 was requested and approved during the summer of 2008, due to delays in availability of products that impacted development and rollout of the planned data collection and management upgrades within SA EMS. The current end date for this project is September 1, 2009 (research ends August 1, 2009).

Body

This section of the report presents discussion and significant accomplishments/problems encountered in the conduct of the subject project during the reporting period. The section is organized to present this information as associated with relevant tasks and subtasks of the modified Phase 2 SOW (dated December 15, 2006), which is the approved SOW version for the subject reporting period.

PHASE 2

TASK 1. To Develop and Implement Incremental Collection and Process Improvements.

Subtask 1.a Collaborate with SA EMS and vendors to facilitate Trauma Vitals data content in developing data management procedures.

Work on this subtask continued during the reporting period. SwRI continued working with Philips Medical Systems, supplier of the new Philips MRx monitor, to expand the understanding of features and operations planned for the data management upgrade under development at Philips.

SA EMS has begun work to implement early incremental features of the planned electronic case data system, and SwRI has continued to work with SA EMS on these upgrades during the reporting period. The SA EMS electronic case data system is currently capable of accepting and storing manual entries by paramedics, filling in data fields in an electronic record, on a laptop computer. Data entries are confined to manual text and numerical entries in selected data fields for case and patient data and areas for case narrative, as manually entered by attending paramedics. The system is constructed around a commercial EMS database product provided by Zoll Data Systems, known as the Tablet PCR EMS data management product.

Philips Medical Systems achieved an initial release of the MRx monitor data management upgrade firmware module and supporting case review software products in late CY2007. Zoll Data Systems and Philips Medical Systems concluded a licensing agreement in early CY2008, to

facilitate planned further development of the Zoll Tablet PCR system to accommodate import of MRx monitor electronic patient data records for use in the electronic case data system. This product has not been fully implemented and the capability to incorporate patient electronic physiological data provided by the Philips MRx monitor within case records is under development.

It is planned that the SA EMS electronic case data system will ultimately import and include data that is acquired during patient triage and care using the MRx patient monitor. However, the Tablet PCR–based electronic case data management system will be focused on producing case records that are compliant with the National EMS Information System (NEMSIS) standards. NEMSIS data standards reflect case summary reports designed to be efficient (for data storage) and will not include much of the data content needed for the Army CCCE program. SwRI has established contact with appropriate staff at Zoll Data Systems to address this concern. SwRI and the Medical Director for SA EMS teamed to work with Zoll Data Systems to reinforce the need to preserve raw data content acquired through use of the MRx monitor. SwRI and the SA EMS Medical Director emphasized the need to also retain the raw MRx monitor data files for each case in order to facilitate retrospective in-depth case review as part of SA EMS operations and quality control, and to facilitate future retrospective research, as needed for the CCCE program. Zoll Data System's response to these requests included plans to preserve the raw monitor data files in compressed form, to be imported and stored with the more general case summary reports in the SA EMS electronic case data system. This step will facilitate future collection and retention of subject study research data and support future retrospective in-depth case review during routine EMS operations.

Subtask 1.b Integrate and adapt evolving monitor and EMS data management in Trauma Vitals pre-hospital patient data collection.

The planned development and rollout of the SA EMS electronic case data system includes plans for a wireless "link-up" between the MRx monitor and the paperless (laptop-based) case reporting system used by each EMS crew in the field. The wireless link approach would provide an opportunity for the SA EMS crew to "near autonomously" extract patient physiological data acquired by the MRx monitor, for each case, and import the patient physiological data into the onboard laptop computer electronic records system. The case summary reports developed within the onboard laptop system, and containing electronic and manually entered (by the crew) case information, would remain stored within the onboard laptop computer until a later time, at which time the "set" of recent case files stored on the onboard laptop would be imported into the SA EMS electronic case data system mainframe computer for further processing and storage. The electronic MRx monitor data would be further processed by the Tablet PCR product within the onboard laptop computer to produce and store the planned NEMSIS compliant case summary report. As reported above, each case summary report is also to preserve and retain compressed versions of the raw MRx data files, usable for retrospective detailed analysis and research. The goal of this work by SA EMS is to facilitate more comprehensive and efficient case summary reporting in electronic format, including electronic storage, maintenance, and access for case summary reports using a dedicated system database.

The Phase 2 project plan includes steps to coordinate enhancements in transparency and efficiency for patient pre-hospital research data collection in support of the CCCE Trauma Vitals program. These advancements are to be enabled by incremental development, rollout, and routine use of the SA EMS electronic case data system. SwRI has continued working with SA EMS, Philips Medical Systems, and Zoll Data Systems to identify opportunities for integration of more efficient and more transparent (to EMS operations) collection of patient data needed for research purposes, as operational improvements in the SA EMS electronic case data system were implemented and rolled-out for routine use in EMS operations. The first candidate enhancement that has been identified focuses on use of the wireless link between the MRx monitor in each ground ambulance and the on-board EMS crew laptop to achieve extraction of, and access to, electronic monitor patient data. This is an important incremental step in the desired ultimate methodology for access and extraction of qualifying research case data from future routine data operations planned by SA EMS. However, during the subject reporting period, the upgrades required to accomplish this functionality within the MRx monitor and the on-board laptop using the Tablet PCR database product have been delayed and are not currently in either benchmarking or general use.

SwRI continues to interact with SA EMS, Philips Medical Systems, and Zoll Data Systems to monitor these developments to further integrate and facilitate the preservation of and access to research data resulting from routine SA EMS operations in the future.

Subtask 1.c Support and collaborate with ISR on Trauma Vitals data research objectives and data mining and visualization methods.

During the reporting period, SwRI continued development and refinement of special data processing algorithms, based on templates and other input provided by USAISR, to provide needed patient monitor data in Extensible Markup Language (XML) data files with data content and format suitable for import into the CCCE program Trauma Vitals database.

The raw MRx monitor data files that contain relevant patient data are produced and stored within the monitor during patient care and are extracted from the monitor retrospectively for project data collection purposes. The improved data extraction algorithms developed by SwRI are also capable of extracting and processing embedded monitor start, stop, and event time information. This information is used to facilitate organization of the needed XML data files for each case, and to facilitate association of each monitor case file and case records developed by SA EMS during each injury response case. The extracted monitor start, stop, and event time data also enable case timing analyses relevant to the hypothesis for the subject study.

SwRI continued meetings with USAISR to better understand current and planned data research capabilities and approaches at USAIR within the CCCE project. Continuing efforts to understand and plan complementary collaboration in data processing and visualization are ongoing at SwRI

TASK 2. To Conduct First Data Acquisition Interval – Manual Data Collect Methods.

Subtask 2.a Develop operational procedures; prepare, train, and coordinate with EMS.

SwRI continued coordination and planning with SA EMS related to procedures and processes for identification of candidate qualifying cases (code 3 adult trauma cases) and for acquisition of relevant raw MRx monitor case data files and SA EMS run-sheet data (without personal identifying information) for the identified cases.

The case selection process for the initial Phase 2 data collection interval was focused on identification of all code 3 injury cases handled by the SA EMS system during the operational period. This information was gathered by frequent sort and review queries on SA EMS dispatch and case records. Further evaluation was required to exclude cases that did not fit the qualified population. Qualifying cases that were ultimately transported by SA EMS to either Brooke Army Medical Center or University Hospital, both Level 1 Trauma Centers operating in San Antonio, were of interest to the study.

Information available from the SA EMS dispatch and case records included identification of the unique SA EMS unit that responded in the case of interest, in addition to an assigned seven-digit SA EMS system case number, date and time information, and case disposition information. The SA EMS seven-digit case number was used to coordinate further work to acquire electronic monitor data with SA EMS, as personally identifiable information was not available.

The patient physiological data collection process required physical access to each ambulance that was involved in each of the identified qualifying cases, retrospectively, in order to gain access to the physiological monitor that was in use during the identified case. The raw data files for candidate cases were then manually selected, based on case time and date information, and extracted from the monitor internal memory and stored on a portable memory card.

SwRI continued development and refinement of algorithms used in extracting and storing the collected raw MRx case data files from monitor memory cards. The MRx monitor files, as stored on the monitor memory card, are labeled with an encrypted alpha-numeric eight-character label and are not readily associable with identified qualifying case time, location, or EMS unit number information. SwRI developed special data transfer algorithms, deployed on a research data acquisition laptop computer which provides the user with extracted SA EMS unit number and monitor start date and time information for each of the raw MRx data files. Once this "case identifier" information is compared with the previously identified candidate qualifying case list, the algorithm provides a prompt to the operator to initiate automatic data transfer from the memory card to the laptop PC. The data transferred to the data acquisition laptop is organized by time and date of the data transfer session from the memory card to the laptop, and the raw MRx case data files are stored within folders labeled with SA EMS unit number and monitor start date and time. SwRI coordinated with consulting SA EMS staff and data collection personnel throughout the data collection interval on refinements to the case identification and data extraction and transfer process.

Subtask 2.b Conduct collection operations for one month, all SA ambulances, 2 hospitals.

SwRI and SA EMS began field operations for the first planned Phase 2 patient data collection interval on April 1, 2007, and continued operations through May 3, 2007. During this 33 day period, data usable within the Trauma Vitals database for 102 qualifying patients was collected and developed. These data demonstrate an average rate of qualifying code 3 injury patients cared for and transported across the SA EMS organization of about three patients per day. This level of operations reflects a significantly high volume of cases for which needed research data can be acquired.

Data collected retrospectively from monitors used in patient care for identified cases was stored on portable memory cards compatible with the MRx monitor. SwRI and SA EMS collaborated continuously during the period of operation to identify and evaluate cases and to transfer acquired electronic monitor data to the SwRI data acquisition laptop PC for temporary storage. The data collected included digital physiologic parameter and waveform data files along with associated monitor serial number, operational data, events, and times. No personally identifiable information was collected during this work.

It is notable that some SA EMS case files include information for multiple patients. This event arises when multiple trauma victims are associated with a single incident. Typically, each code 3 trauma patient is cared for and transported by different responding ambulances. SA EMS case records, however, are developed around incidents as initiated by the 911 call for help. Therefore, SA EMS case files can include information for multiple patients associated with a particular incident.

As the field monitor data collection work proceeded, SwRI and SA EMS also collaborated to collect case run-sheets and case summaries, as routinely generated during SA EMS operations, for identified qualifying cases, with personally identifiable data deleted. Information obtainable from these forms includes the SA EMS 7-digit case number assigned to each case, the unique unit number of the ambulance(s) dispatched for the case, the age of the patients(s) involved, the general type of incident involved, the hospital(s) receiving the patient(s), and the date and time of the EMS 911 call, time of the EMS unit arrival at the scene, and time of EMS unit arrival at the receiving hospital.

Subtask 2.c Review and upgrade SwRI Trauma Vitals data process algorithms relative to developing data content.

During conduct of the first of the three planned one-month data collection intervals for Phase 2, SwRI, working with SA EMS, accessed patient physiological data acquired using the new MRx monitor during patient care and transport retrospectively for each identified qualified patient. SwRI has continued work to enhance the utility and accuracy of the special data processing algorithms based on experience gained during the initial Phase 2 data collection interval. SwRI has also researched and identified process improvements to aid in accuracy of case timing and association efforts. SwRI has continued to research content and format related questions arising from the developing data process techniques. SwRI has continued to use commercially available case reporting software, provided by the monitor manufacturer, to validate data process conversion and output, through comparison of selected output of the commercial product against the output of SwRI-developed data processing tools focused on the needs of the Trauma Vitals

database and the CCCE program. SwRI anticipates that further refinements for the data processing algorithms will be identified and addressed as more experience is gained in processing data acquired during sometimes stressful environments and encountering un-anticipated variables during EMS field operations.

It is notable that some qualified patient cases have been encountered during the initial Phase 2 data collection interval for which the qualified patient was triaged and cared for in the field by SA EMS but the patient was ultimately transported to a hospital by air helicopter services. This typically occurs when a particularly emergent trauma case is encountered and current traffic or other conditions impact the ability to effect a quick transport of an injured patient to a hospital by ground systems. For these patients, electronic pre-hospital physiological data acquired during the early ground care (first responder) interval of the case was collected and processed as described herein, and the resulting Trauma Vitals research data and case information was noted to reflect the ultimate air transport for the respective case. If research electronic pre-hospital patient data is being collected within the respective helicopter service, events such as this may provide an opportunity to merge electronic pre-hospital patient data collected during the early first responder ground care interval and the following helicopter-based care and transport interval to produce research data records spanning the combined intervals.

Qualified patient cases have also been encountered where multiple electronic monitor files are generated during SA EMS care and transport of a single patient. This occurs when the monitor in use is turned off and restarted during the care and transport interval, such as would happen when the monitor batteries become depleted and need to be replaced with spare charged batteries.

Subtask 2.d Associate cases, process, and provide pre-hospital patient data to ISR.

In order to develop the desired research data, SwRI needed to accurately associate identified SA EMS qualifying patient case information with the appropriate electronic digital data files generated by the MRx monitor. This needed to be accomplished without availability of patient personally identifiable information within the records or files.

As previously discussed, responding SA EMS unit number identification and date and time information for each case was derived from SA EMS case records during work to identify potentially qualifying cases for patient data collection. Electronic data files produced for each case using the MRx monitor include unique monitor serial number information within the contents of the data files. In order to accurately accomplish retrospective association between identified qualifying SA EMS case records and electronic data files extracted from the MRx monitors used during patient care and transport by SA EMS, it was useful to correlate individual SA EMS units and the monitors on board the units. This provided confirmation that electronic monitor files under examination for a particular case of interest were correctly linked to the individual SA EMS unit involved in the case.

In order to confirm which MRx monitor files were associated with each SA EMS unit, it was necessary to track the monitor identification (serial number) assigned to each SA EMS unit. A list of EMS units and corresponding MRx monitor serial numbers was compiled to help with his issue; however, the matching of EMS unit number and monitor serial number was subject to

change during the data collection interval. Such changes were usually the result of an SA EMS crew encountering a problem in the use of an assigned monitor and temporarily replacing the suspect monitor with one from a pool of spare monitors till the assigned monitor was returned to service. SwRI and SA EMS collaborated to deal with these variables by including all available spare MRx monitors in the list of monitors used by SA EMS and vigilantly tracking the movement of spare monitors as deployed to EMS units in the field.

Further association between electronic data files extracted from the MRx monitor used in patient care and transport and the SA EMS case record for a case of interest was achieved by examining the date and time of the beginning of the electronic files developed within the monitor during use. The monitor session times contained within electronic files were correlated with the SA EMS records including date and times for the relevant 911 call for help, SA EMS dispatch time, and time of arrival of the SA EMS unit on the scene.

Data files within the monitor memory begin at the time the monitor is turned on and are terminated and stored as the monitor is turned off. The monitor is capable of displaying (on the monitor screen) a list of file folders containing data stored for each monitor operation interval that is labeled with the date and time that the monitor was turned on for each interval. The MRx monitor places start, stop, and event time data within each electronic file generated and stored during use. The time information included in the monitor record is derived from an internal clock, which is not automatically synchronized with the SA EMS dispatch and case tracking system clock. This issue was found to be a source of potential errors or uncertainty in case association and development of case timing relationships for the first few cases for which patient data was collected and processed. SwRI and SA EMS adopted procedures to check the monitor clock setting each time a monitor was accessed for data collection and note time differences between the monitor internal clock and the system clock, and to then synchronize the monitor clock with the system clock if needed. This procedure provided information needed to assess the accuracy of relative timing between events found in the monitor electronic data and the SA EMS case run-sheets and case summary forms for identified qualifying cases, and to apply retrospective corrective factors if needed.

Finally, all electronic files extracted from MRx monitors during the data collection interval were imported into commercially available case summary reporting software provided by Philips Medical Systems, the manufacturer of the MRx monitor. While this tool does not process or retain much of the information required for use in the Trauma Vitals database, it is a useful tool for confirmation of accurate association of SA EMS cases of interest and electronic data files obtained retrospectively from the MRx monitors. The tool displays a list of the MRx monitor files entered, including the monitor serial number, an encrypted case identifier number, the date and time of the beginning of the operation interval, and other information. The tool provides the ability to review the list of cases as a group, sorted by chronological order or by monitor serial number, which is correlatable to a unique SA EMS unit. The ability to examine this summary information for a group of electronic monitor files collected during an increment of time is helpful in cross-checking and confirming case associations based on individual file examination, and in detecting and resolving unusual events such as multiple electronic monitor files generated for a single patient, multiple patients listed within a single SA EMS case file, and manual entry errors or inconsistencies.

The data files collected from the monitor used in the respective EMS unit for an identified qualifying case were typically a set of three to six monitor file folders labeled (on the monitor display) with start times near the anticipated monitor start time, based on knowledge of the SA EMS unit dispatch time and time of arrival at the scene for the identified qualifying case. Electronic monitor files found not to associate with identified qualifying cases were not processed and were deleted from the records.

During the Phase 2 initial data collection interval, SwRI and SA EMS operated to collect and process electronic monitor data for a total of 115 code 3 injury/trauma patients identified as potentially qualified cases. During retrospective analysis, nine patient records were excluded from the study because it could not be established that the patients met age criteria for the subject study. An additional two patient records were excluded from the study because accurate association between the respective SA EMS case records and electronic monitor files could not be adequately established. Excluded cases were not further processed and respective data were discarded. In two injury events, two electronic monitor files were generated within the MRx monitor for each patient, as discussed earlier in this report, and were collected and processed accordingly. In four SA EMS case records, two patients were cared for and transported by different SA EMS ambulances, due to injuries sustained in the same incident. Therefore, SwRI provided a total of 104 processed data files for use in the Trauma Vitals database, reflecting pre-hospital data acquired for 102 qualifying patients.

SwRI provided the electronic pre-hospital data for the 102 qualifying patients as processed for use in the Trauma Vitals database to USAISR. Also, the respective SA EMS run-sheets and case forms that were acquired during the Phase 2 initial data collection interval, without personally identifiable information, were also provided to USAISR for use in the CCCE research program.

In addition to providing relatively high volumes of data for the CCCE research program, the subject study is also focused on beginning pre-hospital patient data acquisition as early in an injury event as is practical. Analysis relevant to the hypothesis proposed for the subject study includes timing analyses for qualifying cases for which patient pre-hospital data was collected and processed and ultimately provided for further research purposes. The Initial Data Delay (IDD), which is defined as the time delay between an injury event and the beginning of acquisition of the pre-hospital monitor electronic data for research purposes, was derived from date and time information contained in the SA EMS run-sheet and case form records and similar information contained within the respective electronic monitor files.

As previously reported, during Phase 1 of the subject study, a limited pre-hospital patient data collection interval was conducted, using a different monitor and a fraction of the ambulances operating in the SA EMS system. Timing analyses were conducted for the 25 qualifying cases encountered during the Phase 1 ground EMS data collection interval and for a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 Trauma Centers by helicopter services. Collaborative comparative analyses by SwRI and USAISR demonstrated that, for these samples, the MIDD time value for the helicopter services was almost 15 minutes longer than the MIDD experienced by the ground SA EMS first responder system. Further

analysis of the variances between the two data sets demonstrated a significant difference between the two groups ($p<0.05$).

Similar analyses were also conducted for the pre-hospital patient data acquired during the initial Phase 2 data collection interval conducted during this reporting period. For this larger data population of 102 qualifying patient cases, the MIDD experienced by the ground EMS first responder system was shorter (approximately 17.5% less delay) than the MIDD obtained during the limited Phase 1 interval. Further analysis between the MIDD obtained during the Phase 2 initial ground EMS collection interval and the MIDD for the previous random cohort of cases transported by helicopter services showed that, for these samples, the ground EMS first responder services experienced a MIDD almost 19 minutes shorter than the MIDD experienced by the helicopter services. Statistical analysis of the data from the 102 qualified patient cases acquired during the initial Phase 2 data collection interval yielded smaller statistical variance and standard deviation values for this data set than for the limited data set collected during Phase 1 ground EMS operations. This demonstrates an even greater significant difference ($p<0.05$) between the data set from the initial Phase 2 ground EMS interval and the helicopter-based data set. A summary of statistical values derived from analysis of the two data populations is presented in Table 1.

Table 1. Statistical Summary of Initial Data Delay Times for Air and Ground Services

	Ground EMS Service Phase 2, 1st interval (n=102); (hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ=Gnd-Air (hr:min:sec)
Mean Initial Data Delay (MIDD)	00:19:11	00:37:59	00:18:48
Standard Deviation	00:06:46.4	00:19:34.8	00:13:11.6
Range	00:35:44	01:28:41	00:52:97
95% Confidence Interval Upper bound	00:20:30	00:43:11	00:22:41
95% Confidence Interval Lower Bound	00:17:52	00:32:48	00:14:56

Key Research Accomplishments

- The Initial Data Delay (IDD) time for qualifying research cases arising from 24/7 operations of the full fleet of ambulances in the SA EMS ground EMS system during the Phase 2 initial one month interval have been determined using data processing and case association techniques refined during the reporting period.

- IDD data acquired for this study during the reporting period within the SA EMS ground EMS system and IDD data resulting from pre-hospital data collection operations within air services were subjected to comparative statistical analyses. The results of this work support the proposed hypothesis for the subject study (see Reportable Outcomes below).

These results are consistent with experience gained during limited previous Phase 1 ground EMS data collection operations.

- Pre-hospital electronic physiological monitor data and corresponding SA EMS run-sheets and case forms for qualifying patient cases were acquired during conduct of the Phase 2 initial data collection interval within the subject reporting period (see Reportable Outcomes below). This data was processed and provided to USAISR for further research purposes.

- Advancements in data conversion have been accomplished based on continued research of the MRx monitor data systems and lessons learned during the expanded data collection and processing operations for the Phase 2 initial data collection interval. The special data processing algorithms are used for extracting and formatting patient case data and relevant monitor configuration and operations information provided by the MRx monitor currently in use by the SA EMS system. The raw files containing relevant patient physiological data are processed and organized into XML reports containing content and formatting usable by the CCCE program. The algorithms also read and process embedded case timing information to facilitate case association and case timing analysis. These improvements facilitate continued provision of qualifying patient pre-hospital data with content and format consistent with the Trauma Vitals database.

- Continued research and development of methodology for accurate association between pre-hospital electronic monitor data files and EMS organization case files, without personally identifiable information, has been accomplished. An array of new variables encountered during the Phase 2 initial interval of operations, within the large municipal SA EMS system dealing with code 3 emergency trauma cases, has been identified. Improvements in data collection and processing methods have been implemented to more efficiently and accurately coordinate electronic monitor data files and SA EMS case summary information, without the availability of personally identifiable information.

- Special algorithms for extraction and acquisition of electronic data files from the MRx monitor in SA EMS field operations have been improved. These developments include automatic labeling of respective electronic folders and files containing pre-hospital patient data to help facilitate coordination between data collection efforts and routine SA EMS operations and reporting, without the use of personally identifiable information.

- A path forward for retention and preservation of raw MRx monitor data within the planned future rollout of the SA EMS electronic case data system has been defined. The raw MRx monitor data files are needed to facilitate retrospective extraction of pre-hospital patient data usable in the USAISR Trauma Vitals database, as well as retrospective in-depth case reviews. SwRI has continued work with the manufacturer of the MRx monitor and the developer of the EMS data management system planned for use in the future SA EMS electronic case data system to maintain visibility and focus on the retention and preservation of the raw monitor data within these systems.

Reportable Outcomes

- Pre-hospital physiological data for 102 qualifying adult code 3 trauma patient cases cared for and transported to Level 1 trauma centers by the entire fleet of SA EMS system was acquired during the subject reporting period. SA EMS run-sheets and case forms for these cases, without personally identifiable information, were also acquired during the reporting period. The data has been processed to conform to the needs of the CCCE database program and delivered to USAISR to facilitate related research activities.

- The IDD was determined for the 102 qualifying ground SA EMS patient cases for which data was collected during the reporting period. The IDD is defined as the elapsed time interval between estimated time-of-injury and the onset of acquisition of pre-hospital patient physiological data for each qualifying case. Data sets from the 102 qualifying ground SA EMS patient cases and from a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 trauma centers by air services were analyzed. Comparative analysis of the two data sets by SwRI and USAISR demonstrated that the helicopter service experienced a MIDD almost 19 minutes longer than the MIDD experienced by the ground EMS first responder system. The operational significance of the shorter IDD experienced in the ground EMS system is that physiological pre-hospital patient data acquisition begins significantly sooner after an injury in the ground system. For these samples, the mean delay of the beginning of data acquisition (MIDD) within the helicopter services was almost twice the mean delay experienced within the ground EMS system. These results are interpreted to substantiate the hypothesis proposed for the subject project.

- Algorithms for extracting and handling raw data for qualifying cases as acquired in SA EMS operations and for processing the raw data to produce data content and formats needed by the CCCE program have been improved. These tools will likely continue to be refined as experience is gained during future data collection operations and as the data management capabilities and procedures are upgraded.

- Methods for field acquisition and preliminary case identification, without personally identifiable data available, have been developed and improved. This methodology is designed to aid in field operations and to provide more efficient and accurate retrospective association between pre-hospital electronic monitor records and SA EMS case records for qualifying cases.

- Work to coordinate project data needs with evolving hardware and software data management capabilities relative to the new MRx monitor and the developing SA EMS electronic case data system has progressed. The need to retain and preserve raw monitor data during routine case data records operation has been established and is reflected in the planning for future SA EMS routine operations.

- SwRI has continued to develop a new initiative, the Parameter-based Remote Objective Pre-Hospital Emergency Triage (PROPHET) program, to support and expand the data collection and research operations that are part of the CCCE program.

Conclusions

Physiological data and trending that can be acquired during the pre-hospital interval of care for seriously injured patients is sought in support of research activities that could yield meaningful advancements in triage and treatment of combat casualties in the field. The U. S. Army's CCCE program includes research elements aimed at advances in triage, treatment, and field decision support systems. Ultimately, knowledge gained from such research could be of benefit to injured patients and care providers in many different types of settings, military and civilian, and especially in mass-casualty situations.

Typically, helicopter-based patient transport systems have provided relatively focused opportunities for pre-hospital access to seriously injured patients for which the data of interest could be collected. This project is focused on exploring the feasibility and advantages of acquiring such data while working within a large municipal ground-based EMS system. The hypothesis proposed for this research is based on the premise that pre-hospital patient data acquisition opportunities will typically begin much earlier in an injury event within a ground EMS first responder system than with helicopter-based services.

The nature of the CCCE program suggests that data reflecting a patient's physiological response to serious injury, beginning as soon as practical after the injury event, could be advantageous in the research program. Analysis of the data acquired, as described in this report, shows that ground EMS first responder systems may provide that "soon as practical" opportunity for acquisition of desired data. Also, the large volume of injury cases typically handled by a large municipal ground EMS system suggests that a relatively high rate of cases of interest could be available to help meet the data needs of the CCCE program, and the data reported herein reflect a relatively large number of qualifying cases encountered during the data collection period.

The planned initial one month data collection interval working with SA EMS, and the related data processing, analysis, and delivery were accomplished during the reporting period. The effort resulted in delivery of pre-hospital patient physiological data files for 102 qualifying patients. The mean delay between the estimated time of injury and the onset of research pre-hospital patient data acquisition (MIDD) for this population of patient cases was 19.18 minutes. This delay is compared to the MIDD experienced for a random cohort of cases within helicopter-based services transporting patients to the same hospitals, of 37.98 minutes or approximately twice the delay experienced within the ground EMS system. Also, the rate of qualifying cases encountered, and for which data was collected, during the ground EMS operations interval is much higher than available within air services.

These findings support the hypothesis proposed for this study and also add significantly to the pre-hospital patient data otherwise available in the Trauma Vitals database in two important areas:

1. The patient data collected and processed in this reporting period, working within the ground EMS first responder system, reflects a data start time occurring much earlier in injury events than data acquired within helicopter-based services. This provides the opportunity to observe and research parameters and trends of interest occurring in a relatively early time window compared with data collected during helicopter-based operations. The "earlier window" of patient data acquired within ground operations can be viewed as complementary to the "later window" of data that can be acquired during air operations. Data from the two modes of operations combined could provide a more complete picture of the parameters of interest than data from either mode alone.

2. The inclusion of data collected within the ground EMS system reflects a large increase in the volume of qualifying cases for which pre-hospital patient data can be acquired during a given time interval. This finding reflects an opportunity to dramatically increase the research patient population in the Trauma Vitals database.

Additional collection of pre-hospital data for qualifying cases is planned, as reflected in the SOW for this project. Two additional data collection intervals working within the SA EMS first responder ground EMS system are to be coordinated with incremental advancements in the developing SA EMS electronic case data system. These developments will ultimately include extraction, processing, and storage of electronic patient monitor data for each case within routine SA EMS operations. The case records resulting from routine operations, however, will contain summary data only, in compliance with NEMSIS standards, and would not normally retain data usable for the Trauma Vitals database. SwRI continued to work with SA EMS, the manufacturer of the physiological monitor, and the developer of the planned EMS case data management system to maintain visibility and support for the subject project research data collection objectives within the evolving EMS organizational case data facilities.

Significant manufacturer delays in development and release of planned data management capability upgrades for the physiological monitor and commercial database products compatible with the monitor, as planned for use in the SA EMS electronic case data system, were experienced during the reporting period. Subject to the manufacturer delays in development of monitor data management tools and the resulting schedule impact on the planned rollout of monitor data parts of the electronic case data system by SA EMS, a no-cost time extension for Phase 2 operations of the subject project through September 1, 2009 was requested and approved. This step was taken in order to allow additional time for developing opportunities for integration of sustainable routine collection of qualifying research data within routine SA EMS electronic case data system operations.

At the conclusion of the subject reporting period, however, delays in availability of data management tools needed for the rollout of the planned EMS electronic case data system capable of processing monitor data continue. As indicated in recent Quarterly Reports, SwRI has begun planning and preparations to exercise contingency plans for data collection during Phase 2 of the project, as discussed as special considerations in the description of the approved Phase 2 SOW. The contingency plans include moving forward with conduct of future planned data collection intervals independent of the evolving, but delayed, rollout of SA EMS routine monitor data

collection operations. SwRI anticipates completion of the planned collection, processing, and delivery of pre-hospital patient data for qualifying cases within the current project period and budget.

Finally, SwRI continues work to develop an initiative based on the subject project to include future automation, expansion, and extension of the data collection and CCCE research. Future plans for the PROPHET program include refinement, automation, extension, and expansion of the data collection efforts. Additional research components will be added to further analyze collected data to help identify meaningful predictive trends and algorithms and to expand data gathering and research work to include additional potential field triage advances. It is anticipated that this work will ultimately lead to deployable prototype equipment, field and clinical trials, and development/distribution of the technologies to military as well as civilian casualty care organizations.